AMENDMENTS TO THE DRAWINGS:

Please replace sheets 1-3, and sheets 5-6 of the original drawings with the attached REPLACEMENT DRAWINGS. A copy of the HAND-ANNOTATED DRAWINGS showing the changes made also is included.

REMARKS

A check for a three month extension of time and an Information Disclosure Statement accompanies this response. Any fees that may be due in connection with the filing of this paper or with this application may be charged to Deposit Account No. 06-1050. If a Petition for Extension of Time is needed, this paper is to be considered such Petition.

A change in Power of Attorney to the undersigned and members of her firm has been filed under separate cover. An assignment to Receptor Biologix, the new owner of this application, has been executed and recordation will be effected.

A copy of the Notice to Comply provided in the Office Action and a replacement Sequence Listing (computer-readable and paper copies) with a verified statement that the contents of the paper copy and computer-readable copies are the same. A supplemental Information Disclosure Statement is filed herewith.

Hand-Annotated Drawings and Replacement Drawings also are filed herewith. The Hand-Annotated Drawings correct obvious minor errors.

Claims 1 and 3-10 are pending in this application. Claim 1 is amended for clarity and in accord with the suggestion of the Examiner. Basis for the amendment of claim 1 can be found throughout the specification. For example, basis can be found at page 4, lines 3-9; and page 5, lines 4-13. Claims 6-10 are added. Basis for these claims can be found throughout the specification. For example, particular basis for claims 6 and 7 can be found, for example, at page 5, line 14, - page 7, line 2; and page 9, line 1, - page 10, line 17. Particular basis for claims 8-10 and can be found, for example, at page 6, line 15, - page 7, line 2. Therefore, no new matter is added.

THE REJECTION OF CLAIMS 1-5 UNDER 35 U.S.C. § 112, FIRST PARAGRAPH – WRITTEN DESCRIPTION

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed subject matter Claims 1-5 remain rejected under 35 U.S.C 112, first paragraph for the reasons set forth in the Office Action, mailed November 1, 2005, at Section 6, pages 3-7. Based upon the Examiner's definition of dependent meaning exclusively needing the support of something to continue to exist, the Examiner urges that the application does provide examples of tumors dependent gastrin-17 in its amidated or extended form. The Examiner indicates that amendment of claims to recite a method for treatment of gastrointestinal tumors "whose growth is stimulated by glycine-extended gastrin 17," will

obviate this rejection. While Applicant does not agree for reasons of record, the claims are amended herein in accord with the suggestion of the Examiner.

THE REJECTION OF CLAIMS 1-5 UNDER 35 U.S.C. §112, FIRST PARAGRAPH - ENABLEMENT

Claims 1-5 remain rejected under 35 U.S.C 112, first paragraph for the reasons of record. The Examiner states that that the rejection may be obviated, for example, by amending claim 1 to recite "A method for the treatment of gastrointestinal tumors whose growth is stimulated by glycine-extended gastrin-17." As above, while Applicant does not agree with the basis for this rejection for reasons of record, amendment of the claims herein should obviate the rejection.

THE REJECTION OF CLAIMS 1-3, 5-8, 13, 14 16, 17, 21 AND 23-26 UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1-5 remain rejected under 35 U.S.C 112, second paragraph, as being indefinite in the recitation of "dependent." It respectfully is submitted that amendment of the claims herein renders this ground of rejection moot.

THE REJECTION OF CLAIMS 1-5 UNDER 35 U.S.C. §102(e)

Claims 1-5 are rejected under 35 U.S.C 102(e) as being anticipated by U.S. Patent No. 5,785,970 as evidenced by Blackmore *et al.* (Int. J. Cancer, 1994,57:385-391) because U.S. Patent No. 5,785,970 discloses a method of treating of a gastro-intestinal disorder by administering to a mammal a therapeutically effective amount of an anti-G17 immunogen, and Blackmore states that cell line HCT-116 is a colon adenocarcinoma cell line (see abstract) and that antagonists to gastrin/CCK receptor, also known as CCK-B receptor, inhibit gastrin dependent growth of the cells, demonstrating that the cell line comprises CCK-B receptors. The Examiner concludes that:

> Although the reference does not teach that the method is drawn to the treatment of glycine-extended gastrin-17-dependent gastrointestinal tumors, the method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering to a mammal a therapeutically effective amount of an anti-G17 immunogen/immunogenic composition comprising an immunogen that is identical to the one exemplified in the instant specification (see Figure 1) to the same population thus the claimed method is anticipated because the method will inherently lead to treatment of glycine-extended gastrin-17-depdent gastrointestinal tumors. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

Reconsideration of the grounds for this rejection is respectfully requested in view of the amendments herein and the following remarks.

Relevant law

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. In re Spada, 15 USPQ2d 1655 (Fed. Cir, 1990), In re Bond, 15 USPQ 1566 (Fed. Cir. 1990), Soundscriber Corp. v. U.S., 360 F.2d 954, 148 USPQ 298, 301, adopted 149 USPQ 640 (Ct. Cl.) 1966. See, also, Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913,1920 (Fed. Cir.), cert. denied, 110 S.Ct. 154 (1989). "[A]ll limitations in the claims must be found in the reference, since the claims measure the invention." In re Lang, 644 F.2d 856, 862, 209 USPQ 288, 293 (CCPA 1981). It is incumbent on Examiner to identify wherein each and every facet of the claimed invention is disclosed in the reference. Lindemann Maschinen-fabrik Gmbh v. American Hoist and Derrick Co., 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984). Further, the reference must describe the invention as claimed sufficiently to have placed a person of ordinary skill in the art in possession of the invention. An inherent property has to flow naturally from what is taught in a reference In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981).

Rejected Claims:

Claim 1 is directed to a method for the treatment of gastrointestinal tumors, whose growth is stimulated by glycine-extended gastrin 17, by administering to a mammal a therapeutically effective amount of an anti-G17 immunogenic composition. The amount of the composition administered is sufficient to inhibit physiological effects of gastrin 17, amidated gastrin and glycine-extended gastrin-17 to effect treatment of the tumor. Dependent claims recite particulars of the tumors or method. Dependent claims 6 and 7 recite additional steps. Claim 6 recites that the method includes assaying a serum sample from the mammal to determine the level of extended gastrin 17 to determine the dosage of the composition for neutralization of gastrin 17 and glycine- extended gastrin 17 to inhibit growth of tumor cells. Claim 7 recites monitoring antibody titer levels against glycine-extended glycine 17 and amidated glycine 17; and administering booster immunizations to maintain an antibody titer effective to neutralize glycine-extended glycine 17 and amidated glycine 17. Claims 8-10 particularly recite methods of passive immunization by administering a sufficient amount of anti-gastrin-17 antibodies to inhibit physiological effects of gastrin 17, amidated gastrin and glycine-extended gastrin17.

All of the claims, thus, require that the method is for treatment of tumors whose growth is stimulated by glycine-extended gastrin 17. In addition, in all claims the amount of

immunogenic composition or antibodies administered is sufficient to not only inhibit gastrin 17, but also glycine-extended gastrin 17 and/or amidated gastrin-17.

Analysis

Disclosure of U.S. Patent No. 5,785,970 and differences from the instant claims

U.S. Patent No. 5,785,970 discloses methods for treating tumors by administering immunogenic compositions for passive or active immunization against gastrin-17. U.S. Patent No. 5, 785,970 discloses a method in which a sufficient titer of antibodies is administered or induced to inhibit binding of gastrin-17 to its receptor on the tumor. U.S. Patent No. 5, 785,970 does not disclose that antibodies against gastrin-17 are reactive with and neutralize amidated gastrin-17 or glycine-extended gastrin-17. U.S. Patent No. 5,785,970 does not disclose that there are tumors that are stimulated by either amidated gastrin-17 or glycine-extended gastrin-17. Hence this patent does not disclose methods for treatment of tumors that are stimulated by these molecules nor methods that include administering an amount of an immunogenic compositions sufficient to inhibit physiological effects of gastrin 17, amidated gastrin and glycine-extended gastrin17 to effect treatment of the tumor. Hence the population treated according to the instantly claimed methods is different from the population treated in U.S. Patent No. 5,785,970. In addition, the amount of composition administered is not disclosed in U.S. Patent No. 5,785,970 to be sufficient for inhibiting the physiological activities of gastrin-17 and glycine-extended gastrin-17 and/or amidated gastrin-17, since U.S. Patent No. 5, 785,970 does not mention these species and speaks to inhibiting binding of gastrin-17 to its physiological receptor. The instant claims require that the amount is sufficient for this purpose. U.S. Patent No. 5, 785,970 does not disclose or suggest inhibition of a species other than gastrin-17. The amount administered as disclosed in the patent is for inhibiting binding of gastrin-17 to its physiologic receptor.

Therefore, U.S. Patent No. 5, 785,970 does not disclose all elements *as claimed.* Thus, it does not anticipate any of claims 1-10.

* * *

In view of the, amendments and remarks herein, reexamination and allowance of the application are respectfully requested.

Respectfully submitted,

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